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ELI LILLY AND COMPANY

By KSR-Hordes

Date 4-24-03

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mark Brader, et al.)
Serial No.: 08/484,542)
Filed: June 7, 1995) Group Art Unit:
For: **Stabilized, Acylated Insulin**) 1631
Formulations) Examiner:
Docket No.: X-10097) M. Allen

DECLARATION OF MR. JONATHAN A. KLEPFER
UNDER 37 C.F.R. § 1.608(b)

Assistant Commissioner for Patents
Washington, D.C. 20231

BEST AVAILABLE COPY

Sir:

Jonathan A. Klepfer declares as follows:

1. I am an employee of Eli Lilly and Company, the assignee of this patent application. I have been employed at Eli Lilly and Company since 1981. I received a Bachelor of Science degree in Medical Technology from St. Joseph's College in 1975. I received a Master of Science degree in Allied Health Education from Indiana University in 1980.

2. I am not a co-inventor in this application. The work I discuss in this Declaration is work I did on behalf of

the inventors on a compound called LY309132. In 1993, I was part of a team that conducted a dose ranging study with compound LY309132 in beagle dogs. The study number was D06893.

3. To generate information on blood glucose and triglycerides in this study, each blood sample was collected into a tube containing no anticoagulant. Serum was obtained by centrifugation, and values for glucose in mg/deciliter were obtained using Monarch™ Chemistry System sold by Instrumentaiton Laboratory, Inc., Lexington, MA.

4. Exhibit 5 is a photocopy of a Clinical Pathology Interim Study Summary Report that I prepared, which sets forth the glucose and triglyceride values for samples that were collected from the six animals at 0, 0.5, 1, 2, 4, 6 and 24 hours after a dose of LY309132 was administered. The original report was printed on September 24, 1993.

5. Exhibit 7 is a photocopy of a Clinical Pathology Interim Study Summary Report that I prepared, which sets forth the glucose and triglyceride values for samples that were collected from the six animals at 0, 0.5, 1, 2, 4, 6, 8 and 24 hours after a dose of LY309132 was administered. The original report was printed on October September 28, 1993. The results for all time points except for the 24 hour time point are shown on the first page of Exhibit 7, and the results for the 24 hour time point are shown on the second page of Exhibit 7.

6. Exhibit 9 is a photocopy of a Clinical Pathology Interim Study Summary Report that I prepared, which sets forth the glucose and triglyceride values for samples that were collected from the six animals at 0, 0.5, 1, 2, 4, 6, 8, 10 and 24 hours after a dose of LY309132 was administered. The original report for all time points except for the 24 hour time point (on the first page of Exhibit 9) was printed on

October 4, 1993, and the original report for the 24 hour time point (on the second page of Exhibit 9) was printed on October 6, 1993.

7. Exhibit 13 is a photocopy of a Clinical Pathology Interim Study Summary Report that I prepared, which sets forth the glucose and triglyceride values for samples that were collected from the six animals at 0, 0.5, 1, 2, 4, 6, 8, 10 and 24 hours after a dose of LY309132 was administered. The original report for all time points except for the 10 and 24 hour time points (on the first page of Exhibit 13) was printed on October 12, 1993. The original report for the 10 and 24 time points (on the second page of Exhibit 13) was printed on October 13, 1993.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information of belief are believed to be true; and I am warned that all statements made herein were made with the knowledge that willful false statements are punishment by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful and false statements may jeopardize the validity of any patent issued from this application.

Jonathan A. Klepfer
Jonathan A. Klepfer

April 23, 2003

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